Membrane Filtration Guidance Manual: Overview and Summary

About This Document

The purpose of this document is to provide a concise summary of the regulatory framework for membrane filtration under the Long Term 2 Enhanced Surface Water Treatment Rule (LT2ESWTR) as presented in the *Membrane Filtration Guidance Manual* (MFGM).

Important Note: This document is not intended to be comprehensive or to serve as a surrogate for a careful and thorough reading of the MFGM, but rather to be used as a convenient reference guide for the core components of the regulatory framework. Furthermore, although this document summarizes the regulatory requirements for the application of membrane filtration under the LT2ESWTR, it is not a substitute for the rule language as published in the Federal Register notice.

Scope and Purpose of the *Membrane Filtration Guidance Manual*

The EPA has developed the LT2ESWTR to reduce the incidence of disease associated with *Cryptosporidium* and other pathogenic microorganisms that may occur in drinking water. The LT2ESWTR supplements existing regulations by mandating additional *Cryptosporidium* treatment requirements for higher risk systems, as determined by source water quality. Systems may satisfy these additional requirements (if applicable) by utilizing one or more of the specified treatment and/or management strategies collectively termed the "microbial toolbox," a range of options that includes membrane filtration. For each of the options comprising the microbial toolbox, the rule mandates a series of requirements specifying the manner in which each option must be implemented for compliance (i.e., in order to receive the potential *Cryptosporidium* removal / inactivation credit associated with each option). The MFGM was developed in conjunction with the LT2ESWTR to elaborate on the rule requirements associated with membrane filtration and to assist utilities with the application of this particular toolbox option for compliance with the rule.

It is important to note that the regulatory framework for membrane filtration developed under the LT2ESWTR and the associated MFGM are only applicable by federal mandate to those systems that employ membrane filtration for the explicit purpose of achieving compliance with the LT2ESWTR. Accordingly, the MFGM is not intended to broadly govern membrane treatment technology or to serve as a general "how-to" guide for membrane filtration systems. However, States may apply the LT2ESWTR framework in a more comprehensive regulatory context, at their discretion, as permitted under their respective primacy agreements with the EPA.

Guidance Manual Organization

The MFGM includes an initial introductory chapter with an overview of the document and summary of the rule requirements (Chapter 1) and three chapters with detailed guidance for complying with each of three primary aspects of the rule: challenge testing, direct integrity testing, and continuous indirect

integrity monitoring (Chapters 3, 4, and 5, respectively). The document also contains a chapter with background information regarding membrane processes for readers less familiar with the technology, particularly as it relates to concepts and terminology essential to a thorough understanding of the rule requirements and associated guidance (Chapter 2). In addition, the MFGM includes three chapters describing recommended and industry-accepted practice in several important facets of developing a membrane filtration facility that are not related to rule compliance (Chapters 6, 7, and 8). Because these latter three chapters do not contain LT2ESWTR regulatory requirements, the associated guidance is not addressed in this summary. An outline of the MFGM is provided in the following table:

MFGM Outline

Chapter	Title	Applicability
Chapter 1	Introduction	Overview / Summary
Chapter 2	Overview of Membrane Filtration	Background Information
Chapter 3	Challenge Testing	Regulatory Requirements
Chapter 4	Direct Integrity Testing	
Chapter 5	Continuous Indirect Integrity Monitoring	
Chapter 6	Pilot Testing	Recommended Practice
Chapter 7	Implementation Considerations	
Chapter 8	Initial Start-Up	

The MFGM also includes several appendices with supplemental information that is applicable to the membrane regulatory framework under the LT2ESWTR:

- Appendix A: Development of a Comprehensive Integrity Verification Program
- Appendix B: Overview of Bubble Point Theory
- Appendix C: Calculating the Air-Liquid Conversion Ratio
- Appendix D: Empirical Method for Determining the Air-Liquid Conversion Ratio for a Hollow-Fiber Membrane Filtration System
- Appendix E: Application of Membrane Filtration for Virus Removal

Membrane Filtration Guidance Manual: Overview and Summary

Overview of Regulatory Framework

Under the LT2ESWTR, systems may be required to achieve as much as 3 log additional *Cryptosporidium* removal and/or inactivation credit depending on the results of source water quality monitoring and the subsequent Bin assignment. Thus, when combined with the prescribed *Cryptosporidium* treatment credit awarded to a system in compliance with the Interim Enhanced Surface Water Treatment Rule (IESWTR) or the Long Term 1 Enhanced Surface Water Treatment Rule (LT1ESWTR), as applicable, the total *Cryptosporidium* treatment credit required for a system in Bins 2, 3, and 4 is 4 log, 5 log, and 5.5 log, respectively. Membrane filtration is one of several toolbox options that has been determined to be capable of achieving the maximum required credit as a stand-alone process. In order to receive *Cryptosporidium* removal credit under the rule, a membrane filtration system must meet the following three criteria.

1. The process must comply with the definition of membrane filtration as stipulated by the rule.

Membrane filtration is defined under the rule as a pressure- or vacuum-driven separation process in which particulate matter larger than 1 μm is rejected by an engineered barrier, primarily through a size exclusion mechanism, and which has a measurable removal efficiency of a target organism that can be verified through the application of a direct integrity test. This definition includes the following membrane processes commonly used in drinking water treatment:

- Microfiltration (MF)
- Ultrafiltration (UF)
- Nanofiltration (NF)
- Reverse Osmosis (RO)

In addition, any cartridge filtration device that meets the definition of membrane filtration and which can be subject to direct integrity testing in accordance with rule requirements would also be eligible for *Cryptosporidium* removal credit as a membrane filtration process under the LT2ESWTR. The MFGM refers to these processes as membrane cartridge filtration (MCF).

2. The removal efficiency of a membrane filtration process must be established through a product-specific challenge test and direct integrity testing.

The rule does not prescribe a specific removal credit for membrane filtration processes. Instead, removal credit is based on system performance as determined by challenge testing and verified by direct integrity testing. Thus, the maximum removal credit that a membrane filtration process may receive is the ***lower*** value of either:

- The removal efficiency demonstrated during challenge testing; **OR**

- The maximum log removal value that can be verified by the direct integrity test used to monitor the membrane filtration process

3. The membrane filtration system must undergo periodic direct integrity testing and continuous indirect integrity monitoring during operation.

The LT2ESWTR requires that the *Cryptosporidium* log removal credit awarded to the membrane filtration process be verified on an ongoing basis during operation. This verification is accomplished by the use of **direct integrity testing**. Currently available direct integrity test methods represent the most sensitive means of detecting integrity breaches, but these tests cannot be conducted on a continuous basis while the membrane filtration system is in operation. Thus, direct integrity testing is implemented at regular intervals and complemented by indirect integrity monitoring, which is generally less sensitive but can be conducted continuously during filtration. This **continuous indirect integrity monitoring** allows for a coarser assessment of membrane integrity in between periodic applications of a more sensitive direct integrity test.

Summary of Rule Requirements

The LT2ESWTR specifies requirements for three critical aspects of implementing membrane filtration for the removal of *Cryptosporidium* in compliance with the rule:

1. **Challenge Testing**
2. **Direct Integrity Testing**
3. **Continuous Indirect Integrity Monitoring**

As a whole, these rule requirements are designed to first establish what *Cryptosporidium* removal credit a membrane product is able to achieve and subsequently how the allocated removal credit for a site-specific system (as determined by the State) is verified on an ongoing basis during operation. The requirements for challenge testing, direct integrity testing, and continuous indirect integrity monitoring are addressed in Chapters 3, 4, and 5 of the MFGM, respectively, and summarized in this document.

Challenge Testing

The *Cryptosporidium* log removal that a membrane product is capable of achieving is determined via challenge testing. Thus, the objective of challenge testing is to ***demonstrate*** *Cryptosporidium* removal efficiency. Challenge testing is intended to be a one-time, product-specific test to establish the maximum *Cryptosporidium* log removal credit that the product is eligible to receive as applied for LT2ESWTR compliance (subject to State approval); however, the demonstrated sensitivity of the site-

and system-specific direct integrity test utilized may limit the maximum log removal credit that can be awarded. Retesting for a specific membrane product may be required if the manufacturer makes significant changes to the product. Guidance to assist membrane manufacturers and State regulators with assessing what types of changes may require retesting is provided in the MFGM. A general overview of challenge testing under the LT2ESWTR is provided in the following table.

Challenge Testing: General Overview	
Description	One-time, product-specific test event designed to demonstrate *Cryptosporidium* removal ability
Purpose	Demonstrate *Cryptosporidium* removal efficiency of an integral membrane product and establish the maximum removal credit that product is eligible to receive
Applicability	Membrane product
Frequency	Once
MFGM Reference	Chapter 3

Challenge testing involves seeding the feed water with *Cryptosporidium* or an acceptable surrogate (i.e., a "challenge particulate") and measuring the log reduction in the concentration of the challenge particulate between the feed and filtrate, as shown in Equation 1.

Challenge Test Removal Efficiency

$$LRV = \log(C_f) - \log(C_p) \qquad \text{[Equation 1]}$$

Where: LRV = log removal value demonstrated during challenge testing
C_f = feed concentration measured during challenge testing
C_p = filtrate concentration measured during challenge testing

The rule requirements associated with challenge testing are summarized in the following table. A detailed explanation of these requirements, along with guidance for compliance, is provided in Chapter 3 of the MFGM.

Challenge Testing: Summary of Requirements	
Topic	**Requirement Synopsis**
Scale of Testing	• Testing must be conducted on a full-scale membrane module or small-scale module that is identical in material and similar in construction
Challenge Particulates	• Testing must be conducted using *Cryptosporidium* oocysts or a suitable surrogate that is removed no more efficiently than *Cryptosporidium* • Challenge particulate concentration must be measured using a method capable of discrete quantification; gross measurements may not be used
Maximum Feed Concentration	• Maximum Feed Concentration = $(3.16 \cdot 10^6)$ x Filtrate Detection Limit
Test Operating Conditions	• Testing must be conducted under representative hydraulic conditions at the maximum design flux and maximum design system recovery specified by the membrane module manufacturer
Removal Efficiency Equation	• LRV = $\log(C_f) - \log(C_p)$
Calculating Removal Efficiency	• Calculate a single LRV value for each module tested • Overall membrane ***product*** removal efficiency: – For sample size < 20 modules: product LRV = lowest value in sample set – For sample size ≥ 20 modules: product LRV = 10^{th} percentile value
Verifying Removal Efficiency for Untested Modules	• Apply a non-destructive performance test (NDPT) to all modules subjected to challenge testing process • Establish a quality control release value (QCRV) from NDPT results that is directly related to the LRV demonstrated during challenge testing • Apply identical NDPT to all modules of that product • Modules not meeting the QCRV are not eligible for the *Cryptosporidium* removal credit demonstrated during challenge testing
Module Modifications	• Additional challenge testing must be conducted for a membrane product that is modified in manner that could affect the established removal efficiency or the applicability of the NDPT, and a new QCRV must be determined
Reporting	• Systems must report the results of challenge testing associated with the membrane filtration system to be used for rule compliance to the State
Grandfathered Data	• All data submitted to the State for grandfathering consideration must originate from studies that can be demonstrated to have been conducted in a manner consistent with the challenge testing requirements of the rule • The maximum credit for which the process is eligible cannot exceed the removal efficiency demonstrated by the grandfathered data

Direct Integrity Testing

After the *Cryptosporidium* removal capability of an integral membrane product is demonstrated via challenge testing, the LT2ESWTR requires that the removal efficiency of a membrane filtration system be verified on an ongoing basis during operation. This verification is accomplished by the use of direct integrity testing. Thus, the objective of direct integrity testing is to ***verify*** that the membrane has no integrity breaches (i.e., leaks) of a magnitude that would compromise the ability of the membrane to achieve the *Cryptosporidium* removal credit awarded by the State. It is important to note that direct integrity testing is not necessarily intended to validate the *Cryptosporidium* log removal demonstrated by challenge testing, but rather the log removal credit that has been awarded to the membrane filtration system by the State, even if the sensitivity of the direct integrity test allows for the validation of a greater log removal value (LRV). A general overview of direct integrity testing under the LT2ESWTR is provided in the following table.

Direct Integrity Testing: General Overview	
Description	Physical testing applied directly to the pathogen barrier associated with a membrane unit (i.e., a rack, a skid, etc.) in order to identify and isolate integrity breaches
Purpose	Verify that the membrane pathogen barrier has no integrity breaches that would compromise the ability to achieve the *Cryptosporidium* removal credit awarded by the State on an ongoing basis during operation
Applicability	Membrane units in a site-specific membrane filtration system
Frequency	Once per day
MFGM Reference	Chapter 4

The LT2ESWTR does not specify the use of a particular type of direct integrity test, but rather allows for the utilization of any type of test meeting the requirements for test resolution, sensitivity, and frequency. The MFGM provides specific guidance for the use of both pressure-based tests (e.g., pressure or vacuum decay test) and marker-based tests (both particulate markers for MF/UF systems and molecular markers for NF/RO systems), the two types of direct integrity tests that are currently in most common use. However, the rule does not preclude the use of other types of direct integrity tests that may be developed in the future, provided the basic requirements for test resolution, sensitivity, and

frequency can be satisfied. It should also be noted that by definition a direct integrity test must ***directly*** test the membrane barrier by some physical means. For example, pressure-based tests apply pressurized air directly to the membrane detect integrity breaches, and marker-based tests involve spiking the feed water to the membrane with a known concentration of a marker to directly challenge the membrane and demonstrate the log removal ability of the process.

In the context of membrane treatment technology, resolution and sensitivity are new terms introduced with the LT2ESWTR and defined as follows:

Resolution: the size of the smallest integrity breach that contributes to a response from a direct integrity test

Note that resolution is expressed as a ***size*** of integrity breach. Because the LT2ESWTR is specifically concerned with *Cryptosporidium*, the rule requires that a direct integrity test must have a resolution of 3 µm, the lower bound of the *Cryptosporidium* size range. For marker-based tests, the resolution requirement dictates that the surrogate (i.e., the "marker") used must have an effective size of 3 µm or smaller in order to demonstrate *Cryptosporidium* removal ability. In order to meet the resolution requirement with a pressure-based test, the net pressure applied must be sufficient to overcome the capillary forces in a 3 µm breach, thus ensuring that any breach large enough to pass *Cryptosporidium* oocysts would also pass air during the direct integrity test. Guidance for determining the resolution of both pressure- and marker-based tests is provided in Chapter 4 of the MFGM.

Sensitivity: the maximum log removal value that can be reliably verified by the direct integrity test associated with a given membrane filtration system

The sensitivity of a direct integrity test is expressed in terms of a ***LRV***, which must be equal to or greater than the *Cryptosporidium* removal credit awarded to the system in order to achieve compliance with the LT2ESWTR. If the direct integrity test used is not sensitive enough to verify *Cryptosporidium* removal on the order of that demonstrated in challenge testing, the sensitivity dictates the maximum removal credit for which the process is eligible. Accordingly, the results of a direct integrity test must be correlated to a corresponding LRV. This correlation is straightforward for marker-based tests, which can use water quality monitoring instrumentation to quantify the concentration of the marker in both the spiked feed and the filtrate under fully-integral conditions. The rule-specified expression for calculating the sensitivity of marker-based direct integrity tests is shown as Equation 2.

Sensitivity of Marker-Based Tests

$$LRV_{DIT} = \log(C_f) - \log(C_p) \qquad \text{[Equation 2]}$$

Where:
- LRV_{DIT} = direct integrity test sensitivity in terms of LRV
- C_f = feed concentration
- C_p = filtrate concentration

The correlation between the results of pressure-based tests and sensitivity (expressed as a LRV) is more complex, given that these types of tests typically yield results in terms of airflow (e.g., mL/min) or rate of pressure change per unit time (e.g., psi/min). The rule-specified expression for calculating the sensitivity of pressure-based direct integrity tests is shown as Equation 3.

Sensitivity of Pressure-Based Tests

$$LRV_{DIT} = \log\left(\frac{Q_p}{VCF \bullet Q_{breach}}\right) \qquad \text{[Equation 3]}$$

Where:
- LRV_{DIT} = direct integrity test sensitivity in terms of LRV
- Q_p = membrane unit design capacity filtrate flow
- Q_{breach} = flow from the breach associated with the smallest integrity test response that can be reliably measured
- VCF = volumetric concentration factor

If the pressure-based test used does not yield results in terms of the flow of water through an integrity breach, these results must be converted in order for Equation 3 to be utilized. Guidance for converting the rate of pressure change or the flow of air through an integrity breach to an equivalent flow of water is provided in Chapter 4 of the MFGM. Additional guidance for determining the volumetric concentration factor (VCF) for a site-specific membrane filtration system is provided in Chapter 2. This parameter accounts for the degree to which some systems concentrate particulate matter in the feed water just above the membrane surface.

A summary of the rule requirements associated with direct integrity testing is provided in the following table.

Direct Integrity Testing: Summary of Requirements	
Topic	**Requirement Synopsis**
Scale of Testing	• Testing must be conducted on each membrane unit (i.e., rack, skid, etc.) in service
Resolution	• The test method used must have a resolution of 3 µm or less
Sensitivity	• The test method used must have sensitivity sufficient to verify the ability of the membrane filtration system to remove *Cryptosporidium* at a level commensurate with the credit awarded by the State • Formulae for sensitivity calculation: – For pressure-based tests: $LRV_{DIT} = \log[Q_p/(VCF \bullet Q_{breach})]$ – For marker-based tests: $LRV_{DIT} = \log(C_f) - \log(C_p)$
Control Limit	• A control limit must be established within the sensitivity limits of the direct integrity test that is indicative of an integral membrane unit capable of achieving the log removal credit awarded by the State • If the direct integrity test results exceed the control limit for any membrane unit, that unit must be removed from service • Any unit taken out of service for exceeding a direct integrity test control limit cannot be returned to service until repairs are confirmed by subsequent direct integrity test results that are within the control limit
Frequency	• Direct integrity testing must be conducted on each membrane unit at a frequency of at least once per day that the unit is in operation • States may approve less frequent testing based on demonstrated process reliability, the use of multiple barriers effective for *Cryptosporidium*, or reliable process safeties
Reporting	• The sensitivity, resolution, and frequency of the direct integrity test proposed for use with the full-scale facility must be reported to the State • Any direct integrity test results exceeding the control limit, as well as the corrective action taken in response, must be reported to the State within 10 days of the end of the monthly monitoring cycle • All direct integrity test results must be retained for a minimum of three years

Continuous Indirect Integrity Monitoring

Indirect methods do not assess the integrity of the membrane barrier directly, but instead utilize water quality parameters as a surrogate to infer information about membrane integrity based on the levels of the monitored parameters relative to the known baseline in a fully integral system. Although indirect integrity monitoring is generally not as sensitive for detecting integrity breaches as the various direct methods, the indirect methods do have the advantage of being able to be applied to continuously monitor

membrane filtrate quality during production, thus providing some means of assessing integrity between direct integrity test applications. Consequently, the objective of continuous indirect integrity monitoring is to ***monitor*** a membrane filtrate system for significant integrity problems between direct integrity test applications. Note that the LT2ESWTR does allow the requirement for continuous indirect integrity monitoring to be waived if a continuous method of direct testing that meets the resolution and sensitivity requirements of the rule is used. A general overview of continuous indirect integrity monitoring under the LT2ESWTR is provided in the following table.

Continuous Indirect Integrity Monitoring: General Overview	
Description	Monitoring some aspect of filtrate water quality that is indicative of the removal of particulate matter
Purpose	Monitor a membrane filtration system for significant integrity problems between direct integrity test applications
Applicability	Membrane units in a site-specific membrane filtration system
Frequency	Continuous
MFGM Reference	Chapter 5

The LT2ESWTR requires filtrate turbidity monitoring (for each membrane unit) as the default method for continuous indirect integrity monitoring. However, alternative methods such as particle counting, particle monitoring, conductivity monitoring (for NF/RO systems), or others may also be approved at the discretion of the State. Independent of the method used, "continuous" monitoring is defined as one reading at least every 15 minutes. The rule specifies a control limit of 0.15 NTU for turbidity monitoring, such that if the filtrate turbidity associated with any membrane unit exceeds 0.15 NTU for a period greater than 15 minutes (i.e., two consecutive 15-minute readings higher than 0.15 NTU), that unit must immediately undergo direct integrity testing. Although control limits for alternative methods are determined at the discretion of the State, two consecutive 15-minute readings exceeding the State-approved control limit for any alternate method would likewise trigger immediate direct integrity testing for the associated membrane unit. A summary of the rule requirements associated with direct integrity testing is provided in the following table.

Continuous Indirect Integrity Monitoring: Summary of Requirements	
Topic	**Requirement Synopsis**
Scale of Testing	• Monitoring must be conducted separately on each membrane unit (i.e., rack, skid, etc.) in service
Monitoring Method	• Continuous indirect integrity monitoring must be conducted using turbidity monitoring unless the State approves an alternative method
Frequency	• Continuous indirect integrity monitoring must be conducted at a frequency of at least one reading every 15 minutes
Control Limit	• If the continuous indirect integrity monitoring results exceed the specified control limit for any membrane unit for a period greater than 15 minutes (i.e., two consecutive readings at 15-minute intervals), direct integrity testing must be immediately conducted on that unit • The control limit for turbidity monitoring is 0.15 NTU • Control limits for State-approved alternative methods must be established by the State
Reporting	• Any continuous indirect integrity monitoring results triggering direct integrity testing, as well as any corrective action taken in response, must be reported to the State within 10 days of the end of the monthly monitoring cycle • All continuous indirect integrity monitoring results must be retained for a minimum of three years

Additional Information

The full text of the *Membrane Filtration Guidance Manual* is available on the EPA website at http://www.epa.gov/safewater/lt2/guides.html. A copy of the Federal Register notice of the final regulation is available from the Safe Drinking Water Act Hotline at (800) 426-4791 – open Monday through Friday, excluding Federal holidays, from 9:00 am to 5:30 pm Eastern Time.